

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

W.R. GRACE & Co.-Conn.,

Plaintiff,

v.

ELYSIUM HEALTH, Inc.,

Defendant.

Civil Action No. 20-1098-GBW

UNSEALED 2/24/2023

MEMORANDUM ORDER

Plaintiff W.R. Grace & Co.-Conn. (“Grace”) accuses Defendant Elysium Health, Inc. (“Elysium”) of infringing U.S. Patent Nos. 10,233,207 (the “’207 Patent,” D.I. 1-1), 10,323,058 (the “’058 Patent,” D.I. 1-2), and 10,189,872 (the “’872 Patent,” D.I. 1-3) (collectively, the “Asserted Patents”). D.I. 1 ¶ 1. On May 5, 2022, Elysium filed an Amended Answer and Counterclaims to Grace’s Complaint for Patent Infringement (the “Answer,” D.I. 113). Pending now is Grace’s Motion to Dismiss Elysium’s Inequitable Conduct Counterclaims and Strike Related Affirmative Defense (the “Motion,” D.I. 136), which asks the Court to dismiss Elysium’s Counterclaims Ten, Eleven, and Twelve and to strike Elysium’s Twelfth Defense. The Court has reviewed the parties’ briefing, D.I. 137; D.I. 152; D.I. 155; D.I. 171, and no hearing is necessary. For the reasons below, the Court denies-in-part and grants-in-part the Motion.

I. BACKGROUND¹

The Asserted Patents claim crystalline Forms I and II of nicotinamide riboside chloride (“NRCl”). See ’207 Patent at Claim 1; ’058 Patent at Claim 1; ’872 Patent at Claim 1. The Court construed (a) “crystalline Form I of [NRCl] according to formula I” in the ’058 Patent and the ’207

¹ The Court accepts as true and views in the light most favorable to Elysium the Answer’s factual allegations. See *Fed. Trade Comm’n v. AbbVie Inc.*, 976 F.3d 327, 351 (3d Cir. 2020).

Patent as “[c]rystalline Form I of [NRCI], according to Formula I, which can be identified by one or more of the analytical methods described in the specification” and (b) “crystalline Form II of [NRCI]” in the ’872 Patent as “[c]rystalline Form II of [NRCI], which can be identified by one or more of the analytical methods described in the specification[.]” D.I. 109 at 1.

Elysium’s initial answer to the Complaint in this action, filed on December 7, 2020, did not include any allegations of inequitable conduct. D.I. 11. A year later, Elysium asked for leave to amend its initial answer to add counterclaims of inequitable conduct, D.I. 59, and proposed text for the amended pleadings, D.I. 59-1. In an oral ruling on April 14, 2022, the Court denied Elysium’s motion. *See* C.A. No. 20-1098, Oral Order of Apr. 14, 2022. The Court explained that Elysium’s proposed pleadings had potentially failed to establish both materiality and intent to deceive the Patent and Trademark Office (“PTO”) and may have failed to adequately tie the inequitable conduct allegations to specific patent claims. D.I. 120 at 73:13–22, 82:19–20. However, the Court permitted Elysium to amend its answer to meet the requirements to prove inequitable conduct. *See* D.I. 120 at 84:10–12, 85:9–20. The Court expressed concern that allegations of “inequitable conduct . . . can be taken advantage of” at trial. D.I. 120 at 86:10–14.

Elysium’s Answer, as amended, includes three counterclaims and one defense that allege inequitable conduct. D.I. 113 at 25, 32–47. Grace moves to dismiss each of them for failure to state a claim on which relief can be granted under Rule 12(b)(6). D.I. 137 at 1. Grace’s first-ranked summary judgment motion (not at issue here) also addresses inequitable conduct. D.I. 191.

II. LEGAL STANDARD

a. Motion to Dismiss Under Rule 12(b)(6)

To state a claim on which relief can be granted, a complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief” Fed. R. Civ. P. 8(a)(2).

Such a claim must plausibly suggest “facts sufficient to ‘draw the reasonable inference that the defendant is liable for the misconduct alleged.’” *Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d Cir. 2022) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). “A claim is facially plausible ‘when the plaintiff pleads factual content that allows the court to draw’” such an inference. *Klotz v. Celentano Stadtmauer & Walentowicz LLP*, 991 F.3d 458, 462 (3d Cir. 2021) (quoting *Iqbal*, 556 U.S. at 678). But the Court must “‘disregard legal conclusions and recitals of the elements of a cause of action supported by mere conclusory statements.’” *Princeton Univ.*, 30 F.4th at 342 (quoting *Davis v. Wells Fargo*, 824 F.3d 333, 341 (3d Cir. 2016)).

“‘The issue is not whether a [counterclaim] plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.’” *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 804 F.3d 633, 638 (3d Cir. 2015) (citation omitted). “‘A motion to dismiss pursuant to Rule 12(b)(6) may be granted only if, accepting all well pleaded allegations in the complaint as true, and viewing them in the light most favorable to [claimant], [claimant] is not entitled to relief.’” *Havens v. Mobex Network Servs., LLC*, 820 F.3d 80, 87 n.12 (3d Cir. 2016) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997)).

b. Inequitable Conduct

“Inequitable conduct is a defense to patent infringement that, if proven, renders the asserted patent unenforceable. ‘To prevail on an inequitable conduct defense, a defendant must establish both [1] the materiality of the withheld reference and [2] the applicant’s intent to deceive the PTO.’” *Belcher Pharms., LLC v. Hospira, Inc.*, 11 F.4th 1345, 1352 (Fed. Cir. 2021) (quoting *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1334 (Fed. Cir. 2012)).

[P]rior art[, for example,] is but-for material information if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. The standard for

establishing but-for materiality in the inequitable conduct context only requires a preponderance of the evidence, giving claims their broadest reasonable construction.

...

To satisfy the intent requirement, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it. Inequitable conduct requires clear and convincing evidence of a specific intent to deceive the PTO and that the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence.

Belcher Pharms., 11 F.4th at 1352–53 (cleaned up). “A finding that the misrepresentation or omission amounts to gross negligence or negligence under a ‘should have known’ standard does not satisfy this intent requirement.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (citation omitted). However, “a district court may infer intent from indirect and circumstantial evidence.” *Id.* at 1290.

“Whether inequitable conduct has been pleaded with particularity under Rule 9(b) is a question governed by Federal Circuit law.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009). “A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b).” *Id.* at 1326–27.

[T]o plead the “circumstances” of inequitable conduct with the requisite “particularity” under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. Moreover, although “knowledge” and “intent” may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.

Id. at 1328–29; see *Analog Devices, Inc. v. Xilinx, Inc.*, 2021 WL 466859, at *1 (D. Del. Feb. 9, 2021) (quoting *Exergen*, 575 F.3d at 1328–29). “A reasonable inference is one that is plausible and that flows logically from the facts alleged” *Exergen*, 575 F.3d at 1329 n.5.

III. DISCUSSION

Grace argues that Elysium fails to plead either but-for materiality or intent. D.I. 137 at 6, 16. Elysium disagrees on both grounds. D.I. 152 at 7, 16. For the reasons explained below, the Court denies-in-part and grants-in-part the Motion. The Court only considers Grace’s pleadings and the exhibits attached thereto. *See* D.I. 155 at 3.

a. Materiality

Grace advances three arguments: First, Elysium failed “to plead facts permitting a reasonable inference that the NRCI allegedly sold contained crystalline Form I and/or Form II NRCI satisfying all limitations of at least one claim of each [of the Asserted Patents].” D.I. 137 at 7. Second, the Answer “makes no effort whatsoever to tie its allegations to specific claims and limitations.” D.I. 137 at 12. Third, Elysium failed “to plead facts from which the Court could reasonably draw the inference that the patents would not have issued but for the alleged omission, i.e., but-for materiality.” D.I. 137 at 14 (cleaned up). Elysium refutes each argument. First, Elysium argues that its pleading establishes that Grace sold crystalline Form I and II NRCI. *See* D.I. 152 at 10–13 (citing D.I. 113 ¶¶ 57–58, 60, 62–63²). Second, Elysium argues that its “allegations are tied to the Form I and II limitations of each asserted claim” and, thus, go to all claims. D.I. 152 at 13–15 (citing D.I. 113 ¶¶ 48, 50, 80, 86, 92). Third, Elysium argues that it alleges evidence to support its assertion that “Grace’s pre-critical date [NRCI] offers/sales” render the claims of the Asserted Patents invalid. D.I. 152 at 15–16 (citing D.I. 113 ¶¶ 73, 76).

The Court agrees with Elysium that its pleading is sufficient to permit a reasonable inference that the NRCI sold included crystalline Form I or II according to the claims. First, all claims of the Asserted Patents either include “crystalline Form I” or “crystalline Form II” or

² Citations to paragraphs of D.I. 113 are to the “Counterclaims” unless otherwise indicated.

depend upon a claim that includes those terms. *See* '207 Patent at Claims; '058 Patent at Claims; '872 Patent at Claims. Second, the Answer alleges that "Batch No. -101" included "'White Crystalline Powder'" NRCI that was made using "certain of the manufacturing processes described in the Asserted Patents[.]" such as dissolution in methanol. D.I. 113 ¶¶ 57–58. Elysium's allegations support that "Grace sold crystalline [NRCI] sourced from Batch No. -101" to a third party "for commercial purposes." *Id.* ¶ 60. Elysium makes similar allegations as to "Batch No. -201." D.I. 113 ¶¶ 62–65. Grace argues that certain evidence attached to Elysium's Answer failed to state that the powder sold was "crystalline" or "white." D.I. 137 at 9–11. Grace also discusses evidence of various differences between the batches Elysium allegedly sold and the Form I and II claimed in the Asserted Patents. D.I. 155 at 2–3. However, the Court must make inferences in Elysium's favor—not Grace's—at the motion to dismiss stage, and, thus, credits the evidence Elysium propounds over that which Grace cites.

The Court also agrees with Elysium that its allegations are tied specifically to the "Form I" and "Form II" limitations in the claims of the Asserted Patents. The Answer alleges that the crystalline NRCI "that Grace offered to sell and sold prior to applicable priority dates of the Asserted Patents contained (a) 'Form I' . . . as claimed in the '207 and '058 patents, and (b) 'Form II' . . . as claimed in the '872 patent." D.I. 113 ¶ 48; *see also* D.I. 113 ¶¶ 80, 86, 92 (similar). Elysium, thus, ties its allegations directly to a specific limitation in each claim of each Asserted Patent. Elysium does not need "analytical data" to support a reasonable inference that the batches allegedly sold contained the Form I or Form II claimed. *See* D.I. 155 at 1, 5 (emphasis omitted).

Third, the Court agrees that the facts alleged by Elysium are sufficient to establish that, but-for omission of the alleged pre-priority date sales, the PTO would not have approved the Asserted Patents. Elysium makes the following allegation.

Information concerning Grace's *pre-application critical date offers to sell and sales* of crystalline [NRCI] would have been highly material to the US PTO patent examiner, since *the on-sale bar (35 U.S.C. § 102) would render claims covering the crystalline [NRCI] offered for sale and sold invalid*. At a minimum, these offers to sell and sales by Grace of crystalline [NRCI] create *a prima facie case* of unpatentability of the claims of the Asserted Patents, which – if it had been disclosed, as required – *would have led the patent examiner to issue a rejection* thereby requiring further investigation into the crystalline [NRCI]; had it been disclosed, as required, this investigation would have occurred while evidence . . . was still easily available.

D.I. 113 ¶ 73 (emphases added). Even if Elysium's allegations about a rejection that resulted from a *prima facie* case are, alone, insufficient to demonstrate but-for materiality, Elysium explains that the sales of crystalline NRCI would have violated the "on-sale bar" and rendered the claims invalid. *Id.* Further, Elysium's statement has factual support and is not conclusory. *See* D.I. 155 at 4–5. The on-sale bar prohibits patenting an invention "on sale . . . before the effective filing date of the claimed invention[.]" 35 U.S.C. § 102(a)(1), or, here and at the earliest, July 24, 2015, *see* '058 Patent. Grace allegedly sold crystalline NRCI in 2013. D.I. 113 ¶¶ 59, 64. Thus, but-for Grace's alleged failure to disclose its sales, the Asserted Patents would have been invalid.

For the reasons described above, the Court finds that Elysium has met the pleading standard for the but-for materiality prong of inequitable conduct to survive at the motion to dismiss stage.

b. Intent

Grace argues that "Elysium fails to plead that any specific individual had the required knowledge and acted with deceptive intent." D.I. 137 at 17. Elysium responds that its pleading "identifies [seven] specific individuals" and that "the most reasonable inference supports Elysium's inequitable conduct counts: these seven were aware of and purposely hid material information from the PTO to obtain allowance of claims that otherwise would have been rejected." D.I. 152 at 17, 19 (citing D.I. 113 ¶¶ 49, 55–63, 68–69, 75). The Court agrees in part with Elysium.

“Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [PTO], which includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability” 37 C.F.R. § 1.56(a). The duty exists while claims are “pending.” *Id.* “This information includes prior sale or public use of the invention one year or more before the filing date of the application.” *Avid Identification Sys., Inc. v. Crystal Imp. Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010). An individual with a duty to disclose “(1) [is] associated with the filing and prosecution of a patent application such that he owes a duty of candor to the PTO, and (2) know[s] that the information [in] question is material.” *Id.* at 973. This Court has found allegations sufficient where “[d]efendants list[ed] a group of inventors by name and allege[d] that each one of the group of individuals engaged in inequitable conduct. These allegations [were] distinguishable from those . . . found deficient when made against unidentified individuals or corporate entities.” *Diebold Nixdorf, Inc. v. Hyosung Tns, Inc.*, 2021 WL 861734, at *3 (D. Del. Mar. 4, 2021) (citations omitted).

As explained above, “[i]nequitable conduct requires clear and convincing evidence of a specific intent to deceive the PTO” that “must be the single most reasonable inference able to be drawn from the evidence.” *Belcher Pharms.*, 11 F.4th at 1353 (cleaned up). However, at the pleadings stage, “an inference of deceptive intent must be reasonable and drawn from a pleading’s allegations of underlying fact to satisfy Rule 9(b)[.]” *Exergen*, 575 F.3d at 1329.

The earliest an Asserted Patent issued was January 29, 2019. ’872 Patent. Elysium alleges inequitable conduct by the named inventors, including Erik Carlson, and by other Grace employees, including Brett Reynolds. D.I. 113 ¶¶ 45, 55. Elysium alleges that Carlson both knew of his duty to disclose to the PTO and signed “batch records” on April 8 and July 22, 2013 that identified pre-priority date crystalline NRCl, which Grace sold to a third party. D.I. 113 ¶¶ 49, 57,

62. Also, a report that Carlson wrote, which is attached as an exhibit to the Answer, identifies sales to the same third party as the “Business Justification” for the creation of the batches. D.I. 113-1, Ex. 2 at -252. These specific facts support Elysium’s allegation that “Carlson . . . intentionally failed to provide the US PTO with . . . these offers to sell and sales.” D.I. 113 ¶ 45. As to Reynolds, Elysium alleges that Reynolds determined on September 25, 2018 that Grace shipped crystalline NRCI to a third party and sent or received emails related to “patent applications” and to “the prosecution and validity of the Grace patents” on July 30, 2018. D.I. 113 ¶¶ 68–69; D.I. 113-1, Ex. 14. Elysium also alleges that Reynolds sent or received emails on September 25, 2018 that concerned “patent protection.” *Id.* While Elysium did not specifically allege that Reynolds knew the crystalline NRCI sold was the Form I or Form II claimed, D.I. 155 at 8, Elysium’s allegations that Reynolds told Peggy Smith not to continue investigating the prior sales, D.I. 113 ¶ 68, combined with emails related to “patent protection” sent the same day support a reasonable inference that Reynolds knew that the batches infringed.

Read in the light most favorable to Elysium, the Court may reasonably infer that Carlson knew of his duty to disclose information to the PTO, knew of the crystalline NRCI that practiced the Asserted Patents in 2013, and intentionally failed to disclose its existence. The Court may also reasonably infer that Reynolds was involved in patent prosecution, determined in September 2018 that Grace had not yet disclosed the crystalline NRCI sales to the PTO, and intentionally avoided such disclosure. Thus, the facts alleged meet the heightened Rule 9(b) standard with respect to Carlson and Reynolds. *See Exergen*, 575 F.3d at 1328–29.³ However, Elysium also alleges that

³ Elysium’s allegations also support a finding that Reynolds’s intent to deceive the PTO is the single most reasonable inference. Grace alleges that “[t]he only possible conclusion” is that Reynolds’s order to Smith not to further research the 2013 batch orders was “because of Grace’s desire to mislead the US PTO” D.I. 113 ¶ 70; *see also* D.I. 113 ¶ 76 (making similar allegations as to Grace as a whole, but not as to individuals). No alternative inference is alleged.

other Grace employees knew of the 2013 batch sales, D.I. 113 ¶¶ 65, 68, or were involved in patent prosecution, D.I. 113 ¶¶ 49, 69, but not both. Thus, Elysium fails to allege specific intent to mislead the PTO as to the other employees.

For the reasons above, the Court finds that Elysium pleads specific intent to deceive as to both Carlson and Reynolds, but not as to other Grace employees.

c. Spoilation

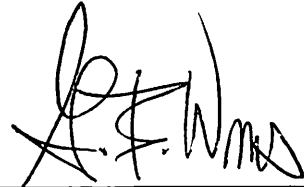
Lastly, Grace contends that Elysium “fails to plead any facts whatsoever supporting” the accusations that Grace destroyed “evidence concerning the crystalline form of the NRCl allegedly sold.” D.I. 137 at 20. Elysium refutes that argument. D.I. 152 at 22. The Court finds but-for materiality and specific intent as to Carlson and Reynolds, above, without this evidence. Further, the evidence Elysium points to of spoilation, D.I. 152 at 22 (citing D.I. 113 ¶¶ 74–75), does not support a reasonable inference of specific intent as to other Grace employees. Thus, the Court need not consider spoilation issues.

IV. CONCLUSION

For the reasons above, the Court denies the Motion as to allegations related to Carlson and Reynolds, but the Court grants the Motion as to all other inequitable conduct allegations.

Therefore, at Wilmington this 10th day of February 2023, **IT IS HEREBY ORDERED** that Grace's Motion to Dismiss Elysium's Inequitable Conduct Counterclaims and Strike Related Affirmative Defense (the "Motion," D.I. 136) is **GRANTED-IN-PART** and **DENIED-IN-PART**:

1. The Motion is **DENIED** to the extent the Motion alleges inequitable conduct by Erik Carlson or by Brett Reynolds;
2. The Motion is otherwise **GRANTED**; and
3. Because the Memorandum Order is filed under seal, the parties shall meet and confer and, within seven (7) days of the entry of this Memorandum Order, submit a joint proposed redacted version, accompanied by a supporting memorandum, detailing how, under applicable law, the Court may approve any requested redactions. In the absence of a timely, compliant request, the Court will unseal the entire opinion.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE